U.S. Food and Drug Administration, Forensic Chemistry Center
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Case/Sample Summary Report

Date: July 19, 2011

From: James A. Turner
Lead Analyst, Organic Branch

Subject: Status Report
OCI Case #: 2010-PHP-715-0519; CIE Serial #: 165500
FACTS #: 677114

To: (b) (7)(F) Special Agent
Philadelphia Resident Office, OCI/FDA

Through: R. Duane Satzger, Ph.D.
Director, Organic Branch

This report presents the results for analyses that have been completed to date. Additional work is being done and a final report will be issued when that is finished.

I. Description of Samples Received for Analysis

The sample was received via UPS on 2/18/2011. The sample consisted of six items which were each described, in part, on CIE 165500. Additional description of the sample is provided in Table 1, below.

II. Analytical Tests Performed on the Samples

Item 3, Item 4, Item 5 and Item 6 were analyzed by one or more of the following techniques: Enzyme-Linked Immunosorbent Assay (ELISA), High Performance Liquid Chromatography / Mass Spectrometry (HPLC/MS), and HPLC/UV (High Performance Liquid Chromatography / Ultraviolet Detection) for purposes of identifying and quantifying drugs that were present. Additional information is provided in Table 1, below.

III. Results of the Analyses

The results of analyses are contained in Table 1 which is presented on pages 2 - 4.

Drugs were identified using HPLC/MS based upon a comparison of the retention time and mass spectral data of a component of the sample with those of a standard which was analyzed under the same conditions. Drugs were assayed using HPLC/UV.

For Item 3, the sample was analyzed using ELISA. The results were consistent with the presence of Human Chorionic Gonadotropin (hCG). This drug was declared on the labeling associated with the Item. This is indicated in Table 1.

The numbers in parentheses in Table 1 represent the 95% confidence interval about the reported assay values.

There was no evidence for the presence of any drugs other than those listed Table 1.

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Results of Analysis CIE 165500 (FACTS 677114) — **Table 1**

Sample	Description of Sample	Technique	Drug Identified / Assay Value
Item 1	Five boxes of product with corresponding labeling, each of which was labeled, in part, "Combipack of Mifepristone and Misoprostol Tablets MTP Kit...A: 1 Mifepristone...200mg ... B: 4 Misoprostol...200 mcg". Two of the five boxes had the following code "Rs.499.00 MASTER B. No.A00618 PRODUCT B.NO.A)A00433 B)A00439 MFD.FEB.10 EXP.JUL.11" and three of the five boxes had the following code "Rs.499.00 MASTER B. No.A00834 PRODUCT B.NO.A)A00585 B)A00579 MFD.MAR.10 EXP.AUG.11". Each box contained one intact blister-pack with four Misoprostol tablets and one Mifepristone tablet.	Analysis ongoing	Analysis ongoing
Item 2	Twelve boxes of product with corresponding labeling and codes each of which was labeled, in part, "Artesunate Injection...Artesunate 60 mg". Each box held one clear vial with an intact reddish brown metal crimp cap labeled, in part, as the box and containing a white powder; one intact clear ampoule labeled, in part, "Sodium Bicarbonate Injection IP"; and one plastic ampoule labeled, in part, "SODIUM CHLORIDE INJECTION IP".	Analysis ongoing	Analysis ongoing

	Falcigo Vial	Sodium Bicarbonate Ampoule	Sodium Chloride Ampoule
Batch No. :	AFI1074	2690011	7210849
Mfg. Date :	09/2009	08/2009	06/2009
Expiry Date :	02/2011	07/2011	05/2014

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Results of Analysis CIE 165500 (FACTS 677114) — **Table 1 (continued)**

Sample	Description of Sample	Technique	Drug Identified / Assay Value
Item 3	Five boxes of product with corresponding labeling and codes each of which was labeled, in part, "Chorionic Gonadotrophin Injection I.P. (Human Chorionic Gonadotrophin Injection)...5000 I.U.". Each box held one clear vial with an intact green flip cap labeled, in part, as the box and containing a white powder and one intact amber ampoule labeled, in part, "Sodium Chloride Injection I.P." and containing a clear colorless free-flowing liquid. Two of five of the boxes/vials of product were analyzed – more specifically, only the Human Chorionic Gonadotropin (hCG) labeled vials were analyzed.	ELISA	The data is consistent with the presence of Human Chorionic Gonadotropin (hCG) (Assay work ongoing)
Item 4	Five intact blister-packs of product with corresponding labeling and codes each of which was labeled, in part, "Sildigra...Sildenafil Citrate 100 mg...B.No.SGSG 1004 MFG.AUG. 2010 EXP. JULY 2012...". Each blister-pack held ten grey unmarked soft-gel capsules. Five capsules from one of five blister-packs were analyzed.	HPLC/MS And HPLC/UV	Sildenafil at 72 (± 4) mg/capsule *(This is equivalent to 102 (±6) mg/capsule as Sildenafil Citrate)*

	hCG Vial	Sodium Chloride Ampoule
Batch No. :	A6110004	A6610009
Mfg. Date :	03/10	03/10
Expiry Date :	02/13	03/15

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Sample	Description of Sample	Technique	Drug Identified / Assay Value
Item 5	Five intact blister-packs of product with corresponding labeling and codes each of which was labeled, in part, "FILAGRA 100…Sildenafil Citrate Tablets 100 mg…B.NO.T89012 M.D.OCT.2010 E.D.SEP 2013…". Each blister-pack held ten diamond (bi-pyramid) shaped tablets with the following debossing "DP" and an oval shape on one side and "FGR-100" on the other side. Five tablets from one of five blister-packs were analyzed.	HPLC/MS And HPLC/UV	Sildenafil at 100 (± 8) mg/tablet
Item 6	Five intact blister-packs of product with corresponding labeling and codes each of which was labeled, in part, "TAdALiSTA…Tadalafil 20 mg Tablets…B.NO.798015 M.D.OCT.2010 E.D.MAR.2013…". Each blister-pack held ten unmarked yellow oval shaped tablets. Five tablets from one of five blister-packs were analyzed.	HPLC/MS And HPLC/UV	Tadalafil at 19 (± 2) mg/tablet

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IV. Sample Retention/Disposition/Feedback Information

This evidence will be retained by the Forensic Chemistry Center pending notification of disposition from your office. If you have any questions, concerns or need additional information, please do not hesitate to contact me at (513) 679-2700 Ext. 2240, or you can contact Kevin J. Mulligan, Ph.D. at (513) 679-2700 Ext. 2238.

James A. Turner

Section Author's Concurrence

Section 681: for Tim Y.
Timothy Yi

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Reviewer:
Kevin J. Mulligan, Ph. D.